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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,957	11/13/2001	Hans Herweijer	Mirus.025.01	8989

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/992,957

Applicant(s)

HERWEIJER ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-12 and 25-27.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Continuation of 2. NOTE: Claim 1 has been amended to add part (e), which recites that the method steps set forth in the claim generate in the mammal an immune response selected from immunization, vaccination, induction of a cellular immune response, induction of a humoral immune response, production of antibodies specific to the antigen and producing immune cells that produce antibodies to the antigen. The previously examined claim required only that the method induce an immune response and did not require any of the particular responses recited in the amended claim. As the amended claim adds limitations that must be newly searched and evaluated for compliance with 35 USC §112, the amendment raises new issues that would require further search and examination and does not simplify the issues for appeal. Likewise, the proposed amendment to claim 25 provides an additional process step wherein antibodies or immune cells producing antibodies are isolated from the rodent into which the nucleic acid is delivered. As the method comprising this process step was not previously examined, the amendment raises new issues requiring an additional search.

Continuation of 5. does NOT place the application in condition for allowance because: First, it is noted that the amendments would overcome the objections to claims 1 and 25 and the rejection under 35 USC §112, first paragraph.

Regarding the outstanding art rejections, to the extent that Applicant's arguments are predicated upon entry of the amendment, the arguments are moot. However, it is noted that the proposed amendment to claim 25 does not distinguish the claims from the art. The amended claim merely recites outcomes, which, absent evidence to the contrary, are presumed to be inherent to the method disclosed in the art. The art teaches a method that anticipates the method steps set forth in parts (a)-(d) of the claim; therefore, the outcome recited in part (e) must be inherent to the method unless the art is not enabling for that outcome. Although Applicant argues that Liu et al. and Zhang et al. provide no evidence that they were aware of an immune response resulting from their method, Applicant is reminded that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999). MPEP 2131.01. As stated in the final Office Action, "[a]lthough Liu et al. does not explicitly teach inducing an immune response, Liu et al. teaches expression of luciferase in various organs and tissues of mice, which is demonstrated in Example 5 of the instant application to elicit an antibody immune response. The specification teaches that the antibody response obtained by the method, "is not surprising given the large amount of antigen that is produced" (page 41, line 20-21)." Thus, the extrinsic evidence supports the inherency of some immune response within the scope of the instant claim elicited by the method of Liu et al. and Zhang et al.

Applicant cites art that allegedly evidences a suppressed immune responsiveness of the liver as compared with other tissues. However, while the art does suggest that expression of antigen in liver alone might lead to tolerance rather than an immunization against the antigen, the art does not assess immune responses to systemically delivered plasmid encoded antigen as provided in the method of Liu et al. and Zhang et al. In contrast, the instant application teaches that such systemic administration does, in fact, lead to an immune response. Although Applicant argues that the statement from the specification cited in the Office Action "does not constitute an obvious expectation of the initial result", the findings provided in the example support the inherency of the immune response regardless of whether one would, a priori, expect the result.